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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.            | CONFIRMATION NO. |
|---|-------------|----------------------|--------------------------------|------------------|
| 09/826,482  | 04/04/2001  | John C. Carson       | A17-045                        | 6243             |
| 7590 03/29/2005<br>COLEMAN SUDOL SAPONE, P.C.<br>714 COLORADO AVENUE<br>BRIDGEPORT, CT 06605-1601 |             |                      | EXAMINER<br>VENKAT, JYOTHSNA A |                  |
|   |             |                      | ART UNIT<br>1615               | PAPER NUMBER     |

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                          |               |  |
|------------------------------|--------------------------|---------------|--|
| <b>Office Action Summary</b> | Application No.          | Applicant(s)  |  |
|                              | 09/826,482               | CARSON ET AL. |  |
|                              | Examiner                 | Art Unit      |  |
|                              | JYOTHSNA A. VENKAT Ph. D | 1615          |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

Receipt is acknowledged of amendment filed on 10/18/04 and 11/26/04. Claims 1-3 and 5-30 are pending in the application and the status of the application is as follows.

Taking preamble into consideration, the rejection of claims 1, 8, 11, 13, 16 and 22 under 102(b) over U. S. Patent '305 is withdrawn.

1. Claims 1-2, 5-6, 8-21, and 24- 26, 28-29 are rejected under 35 U.S.C. 102(b) as being anticipated by U. S. Patent 6,043,204 ('204).

See col.4, line 64 for the claimed octyl methoxy cinnamate which is the claimed high density aromatic ester of claim 25, see also col.5, lines 44-45 for octyl salicylate which is also the claimed high density aromatic ester of claim 24, see col.6, lines 5-45 for the claimed surfactants and also anionic surfactants of claims 11-14, see col.8, line 35 for lactic acids, glycolic acids which are used in the cosmetic art as exfoliating agents and it reads on the claimed exfoliating agents, see also the same column, lines 32-33 for the claimed penetration enhancers which are “ propylene glycol, butylene glycol and glycerin”. See col.7, lines 45-67 for the claimed low-density oil. See the title, examples and claims for body cleansing, which read on the claimed “body cleanser” .Since the components, are same, claims 6-6, and 16-17 are inherent.

The specification at page 8 defines the term “phase” as “*phase means a distinct layer which appears in compositions according to the present invention after a sufficient settling period (preferably, at least about 1 minute, more often about 5 minutes or more up to about 30 minutes, and in certain embodiments, up to several days or more). Compositions according to the present invention comprise two, three or four distinct phases or layers.*”

Therefore the patent anticipates the claims absence of evidence to the contrary

***Response to Arguments***

2. Applicant's arguments filed 11/26/04 have been fully considered but they are not persuasive.
3. Applicants' argue that there is absolutely no evidence in patent '204 that provides a disclosure which produces the presently claimed invention and contrary to the Examiner's contention, the composition of table 2, example 12 does not give rise to the present invention because that composition is a completely mixed product which does not separate upon settling since that example is a composition, which is a homogeneous emulsion, completely unlike the present invention and having only a single visual phase. Applicants also argue that there is no evidence in example 12 that in order to use the product one mixes the visually separate layers- precisely because there is no need to mix the homogenous emulsion produced and there is simply no credible way that the composition of example 12 may be construed to be directed to a composition according to the present invention which settles into at least two visually distinct layers after mixing and consequently, Kaufman cannot be read to anticipate the present invention.
4. In response to the above argument, it is the position of the examiner that the claims of the instant application are drawn to " composition" and not to method of making the composition (emphasis added). With respect to applicants arguments that there is no evidence in example 12 that one mixes the separate layers, it is the position of the examiner that the specification under **all the examples teaches adding the ingredients together and the layers are formed after shaking.** Applicants did not present any evidence in response to the last office action that the

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examples disclosed in the patent **did not** appear as at least two discrete and separate layers which appear upon settling after mixing the compositions. Therefore the 102 (b) rejection is deemed proper.

The claims have been amended from “*comprising*” to “*consisting essentially of*”.

The transitional phrase “consisting essentially of” limits the scope of a claim to the specified materials or steps “and those that do not materially affect the basic and novel characteristic(s)” of the claimed invention. In re Herz, 537 F.2d 549, 551-52,190 USPQ 461, 463 (CCPA 1976) (emphasis in original). **If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of “consisting essentially of,” applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant’s invention.** In re De Lajarte, 337 F.2d870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061,1063-64 (Bd. Pat. App. & Inter. 1989)

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-3,5-21 and 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of US 2002/20160023(PGPUB '023) and U.S. Patent '204.

*The instant application is a claiming compositions comprising “*

*1. High density aromatic ester*

*2. Surfactant*

*3. Oil*

*4. Exfoliating agent.*

The PGPUB '023 teaches multi phase formulations. See examples 1 and 2 for three phase and four phase formulations. The document teaches penetration enhancers at page 1, col.1, last paragraph and col.2, paragraph6and oils at paragraphs 7- 8, and exfoliating agents at paragraphs 14-14. The patent at paragraph 15 suggests the incorporation of sunscreens (claimed high density esters). The difference is the document does not teach surfactants. However the patent '204 teaches surfactants in the body cleansing compositions along with other ingredients claimed.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare multiphase compositions of PGPUB document and add the claimed sunscreens and surfactants of '204 expecting beneficial effect to the skin. The motivation to add the surfactants stems from the scientific knowledge that surfactants are used mostly in cleansing compositions and the motivation to add the sunscreen into the composition

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stems from the '204 that these compounds provide protection against sun. One of the ordinary skill in the art would expect reasonable amount of success that by combining the surfactants and sunscreens into the compositions of PG PUB document, the compositions not only exhibit cleansing property but also protection against sun. This is a prima facie case of obviousness.

***Response to Arguments***

8. Applicant's arguments filed 11/26/04 have been fully considered but they are not persuasive.

9. Applicants argue that the PG PUB document and perhaps hundreds of patents and other references in the cosmetic filed, discloses the preparations of formulations by first preparing a composition in separate phases and then mixes the phases together to form a final formulation or composition and the PG PUB document does not disclose or suggest that the phases should separate into at least two distinct layers upon settling.

10. In response to the above argument, it is the position of the examiner that the PG PUB document teaches two-phase cosmetic compositions. It is indeed true that the PUG PUB document is silent to the separation of phases upon settling, upon mixing the formulation, however the specification at page 8 defines the term "phase" as *"phase means a distinct layer which appears in compositions according to the present invention after a sufficient settling period (preferably, at least about 1 minute, more often about 5 minutes or more up to about 30 minutes, and in certain embodiments, up to several days or more). Compositions according to the present invention comprise two, three or four distinct phases or layers.* Therefore it is the position of the examiner that when the formulations are mixed they will again separate into layers when they are left for several days or more. The patent under example 1 teaches the

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mixing of the phases by heating. If there is no heating the phases might be separated into layers after settling, when mixed.

11. Applicants' argue that there is absolutely no evidence in patent '204 that the compositions disclosed therein are thoroughly mixed prior to use, a two-layered composition is not even mentioned by the patent and there is absolutely no disclosure in the patent which would motivate one of ordinary skill to produce the present compositions- indeed the concept that gives rise to the present invention- that of allowing two visually distinct layers to form upon settling after mixing.

In response to the above argument, it is the position of the examiner that that one of ordinary skill in the art would certainly be motivated to add surfactants and sunscreen agents of '204 into the compositions of PGPUB expecting that the compositions exhibit both the cleansing property as well as protection against sun. It is indeed true that the both the references are silent to the separation of phases upon settling, upon mixing the formulation, however the specification at page 8 defines the term "phase" as *"phase means a distinct layer which appears in compositions according to the present invention after a sufficient settling period (preferably, at least about 1 minute, more often about 5 minutes or more up to about 30 minutes, and in certain **embodiments, up to several days or more**). Compositions according to the present invention comprise two, three or four distinct phases or layers. Therefore it is the position of the examiner that when the formulations of the both the references are mixed, **they will separate into layers after a sufficient settling period**, since applicants did not present any evidence to the contrary with regard to 102(b) rejection. Therefore the 103 rejection is deemed proper.*



12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

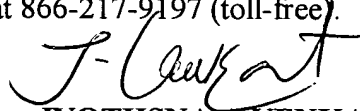
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **JYOTHSNA A. VENKAT Ph. D** whose telephone number is 571-272-0607. The examiner can normally be reached on Monday-Friday, 10:30-7:30; 1st Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **THURMAN K. PAGE** can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**JYOTHSNA A VENKAT Ph. D**  
**Primary Examiner**  
**Art Unit 1615**

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